

On being common

"The Lord prefers common-looking people. That is why he made so many of them." So apparently, said Abe Lincoln. Well, someone made a whole lot of common health problems as well. Some of those common, but serious, conditions, like heart disease or diabetes, deservedly attract a lot of attention. But there are common conditions that do not. Bandolier has tried to make a habit of looking for those common, but overlooked, conditions.

Much in these columns this month is devoted to the common, starting with a useful review of treatments for earwax, a topic of great interest to Bandolier. Earwax is probably a good idea, but perhaps not in abundance. The review tells us that there is little known to be better than simple remedies, and there are few trials. Another systematic review, of constipation prevalence in North America, claims to be the first of its kind.

Mismatched research

What do people want from research? Answers to things that affect them might be one answer. Given that earwax is a problem that affects many, how come there is no super-whizzo ear drop that is simple to use, safe, and effective? Just think of time saved by doctors and nurses syringing ears if there was something we could buy ourselves.

Often research hits the right buttons. Two observational studies are worth a read because they hit the spot. One charts how people with hip or knee problems in the UK are handled, while another, from Germany, demonstrates how the problem of latex allergy in healthcare workers can be overcome by simple interventions well implemented. Another systematic review of (mainly) observational studies on surgery for obesity shows how useful this can be. Pride of place, though, to a superb randomised trial of intravenous immunoglobulin in one form of MS, that answers the question of whether or not it works.

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TREATING EARWAX

It is awfully embarrassing visiting your doctor complaining about progressive deafness, only to be told that your ears are blocked with wax and need syringing. Earwax is probably useful for something, but it is tiresome stuff. Earwax removers even appear in all those Roman medical kits found in archaeological excavations. Dealing with earwax is a long-standing problem, so a systematic review [1] of preparations to help deal with it should make life easier.

Systematic review

Four electronic databases were searched up to June 2003 for trials, earwax experts contacted, and manufacturers of preparations asked for clinical trials. For inclusion trials had to evaluate eardrops in properly randomised trials, and the drops could be of any type. The outcomes chosen and relevant were those of clearance of earwax without syringing, or the outcome of successful syringing after treatment.

Results

Eighteen trials were found, all more than 10 years old, and some were published as long ago as the 1950s. Four trials were regarded as high quality (maximum scores for allocation sequence, concealment, inclusion of all patients, and blinding), and most were small. Many treatments were compared in only one trial.

The small number of patients and trials means that statistical analysis is probably inappropriate. Results below are therefore the pooled percentage success rates from at least two trials, with the numbers of patients in parenthesis.

Clearing earwax without syringing

Figure 1 shows available information. Based on small numbers, preparations containing docusate or triethanolamine polypeptide had about the same efficacy as saline. None was more than 20% effective in clearing earwax without syringing.

Figure 1: Ears cleared spontaneously (number of patients)

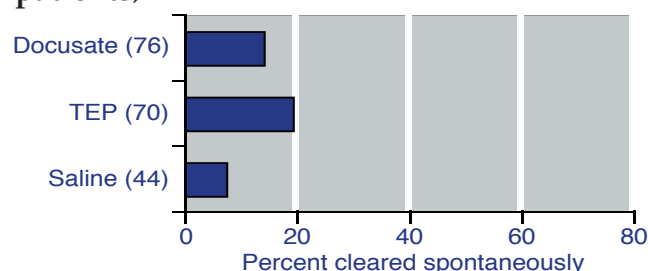
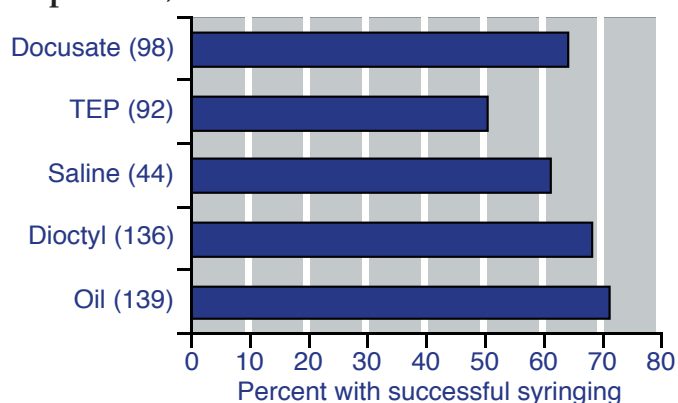


Figure 2: Ears successfully syringed (number of patients)



ing. Treatment for four days may be better than treatment for shorter periods, but evidence is not extensive.

Successful syringing

Figure 2 shows available information. Based on small numbers, preparations containing docusate or triethanolamine polypeptide had about the same efficacy as saline. Dioctyl was about the same as maize oil or olive oil, but these oil-based treatments were no different from water-based treatments. All were about 60-70% effective in clearing earwax without syringing. Treatment for 30-60 minutes was as effective as longer periods.

Comment

There we have it. No one treatment is demonstrably better than any other in a series of trials. There is very weak evidence that a choline and glycerol product may be better than average for both outcomes, but there is just not enough trial evidence. Nor were rare and possibly serious adverse events looked at. Earwax removal procedures resulted in chronic tinnitus in 11 of 2,400 (0.5%, or 1 in 200) consecutive patients in one survey [2].

This lack of evidence is disappointing. There just isn't enough evidence about which to be certain, but if you use saline or olive oil it is unlikely that there is anything better. Anyone who thinks their product is better had better find a way of proving it.

Two randomised trials have been published since the search in 2003. One [3] found no difference between docusate, triethanolamine polypeptide or saline in visualising tympanic membrane in children aged six months to five years. The other [4] found no difference between triethanolamine polypeptide, carbamide peroxide, and saline followed by low pressure water irrigation (though saline did best).

On one hand we are probably not that much further on from our Roman ancestors with their olive oil and spatulas. On the other, when that jet of warm saline makes us feel that any wax is coming out the other ear, we can at least take solace from the fact that there is nothing else known to be a better alternative.

References:

- 1 C Hand, I Harvey. The effectiveness of topical preparations for the treatment of earwax: a systematic review. *British Journal of General Practice* 2004 54: 862-867.
- 2 RL Folmer, BY Shi. Chronic tinnitus resulting from cerumen removal procedures. *International Tinnitus Journal* 2004 10: 42-46.
- 3 VN Whatley et al. Randomized clinical trial of docusate, triethanolamine polypeptide, and irrigation in cerumen removal in children. *Archives of Pediatric and Adolescent Medicine* 2003 157: 1177-1180.
- 4 PS Roland et al. Randomized, placebo-controlled evaluation of Cerumenex and Murine earwax removal products. *Archives of Otolaryngology Head and Neck Surgery* 2004 130: 1175-1177.

CONSTIPATION PREVALENCE (STRANGERS TO THE LAVATORY)

What is common? Apparently, back in 1965 around 99% of factory workers in the UK had a bowel frequency of between three times a week and three times a day (3-21 movements a week), and this has been a rule-of-thumb standard definition. A systematic review of laxative treatments in Bandolier 46 had the number of weekly bowel movements with placebo in the range of 1-7, mostly below five a week, which fits with that. But straining, hard stools, incomplete evacuation and other aspects of impaired defecation are important.

A systematic review of the prevalence of constipation in a North America [1] takes not just definition into account, but also issues around sex, race, age, and other factors, to try and tease apart how these might influence constipation prevalence estimate.

Systematic review

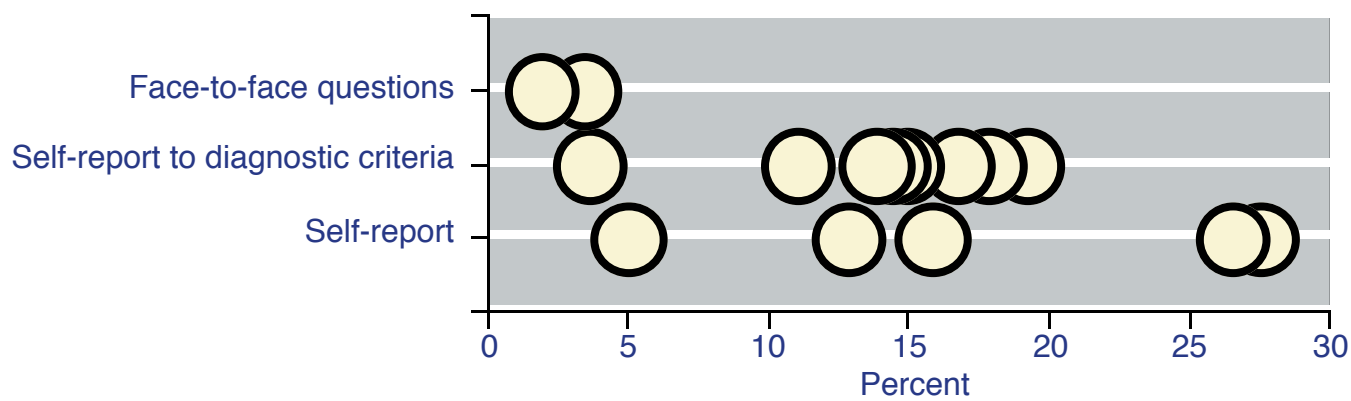
The search was for studies published up to about the end of 2002, and used three electronic databases and manual

searches of reference lists. Selection criteria included population-based studies of North American populations, in adults, reporting prevalence of constipation, in full English-language publications.

Definitions of constipation allowed were self-report by subjects, physician or coded diagnosis, or standardised definitions. One, for instance, included 12 weeks or more of the following:

- Fewer than three stools per week
- Hard or lumpy stools with at least a quarter of bowel movements
- Straining with at least a quarter of bowel movements
- A sense of incomplete evacuation in at least a quarter of bowel movements
- A sense of anorectal obstruction with at least a quarter of bowel movements

Figure 1: Constipation population prevalence in adults, according to method of ascertainment



Results

Ten reports were included (USA and Canada), over the years 1964 to 2000. Populations studied ranged from about 700 to nearly 900,000. Self-report of constipation was the most commonly used definition, with self-reported answers to defined questions next most common, with two studies using face-to-face questions as part of a census.

The overall average percentage of people with constipation was about 15% (1 in 7 adults). The range was 1.9% to 27%, shown in Figure 1 according to how constipation was ascertained. Most reports were in the range of 12% to 19%, with some self-reported prevalences being higher, and both face-to-face questioning reports below 4%.

There was a distinctly higher prevalence in women compared with men in almost every study, irrespective of method of ascertainment (Figure 2). Prevalence of constipation in women was on average about twice as high as in men. There was also a consistent finding of higher constipation prevalence in non-Caucasian people, by a factor of about 1.4 to 1, though non-white racial groups were not subdivided.

Other trends were for decreased prevalence in people with highest income and highest educational attainment or years of education, though these may well be measuring different aspects of the same phenomenon. Older age, especially age over 70 years, was also associated with higher constipation rates. Because different age ranges were reported the results

Figure 2: Constipation prevalence in men and women

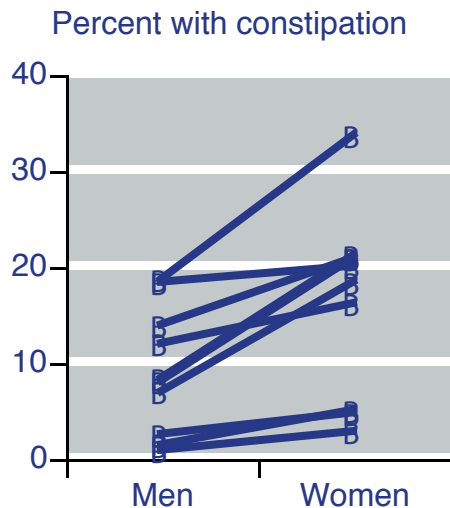
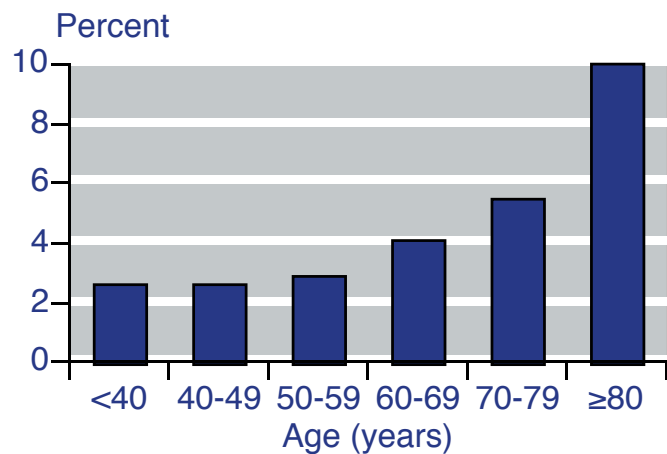


Figure 3: Constipation by age in one study



were not consistent between studies, but an example from a study using face-to-face questioning is shown in Figure 3.

Comment

How many adults in industrialised countries have constipation? The answer is about 1 in 7. Though this review looked only for North American studies, the results are probably much the same in any industrialised country with western diets and behaviour patterns. What is interesting is a general consistency of result in terms of overall population, and effects of sex, race, and age, despite studies using different ascertainment methods and criteria, different study size, and sampling over about 35 years.

Constipation is not fun. Diet, especially fibre, and exercise can promote better bowel habit, and perhaps the finding of lower constipation prevalence with income and years of education reflects better adherence to healthy lifestyles by the more educated and better off. Lots of people must spend money on products from the pharmacist, or see their doctor for a prescription for a laxative.

Perhaps constipation avoidance should be yet another topic that goes onto the healthy living list, associated with good diet and moderate exercise. Bandolier will look for more evidence of that.

Reference:
1 PD Higgins, JF Johanson. Epidemiology of constipation in North America: a systematic review. American Journal of Gastroenterology 2004 99: 750-759.

TREATING HIP AND KNEE ARTHRITIS IN THE UK

Healthcare isn't just about interventions, but also about delivering care. It is about what happens in the real world, and if you want to make things better you really have to start with a clear picture of that real world. Asking experts, or coalface professionals, or both, is the way we usually get our snapshot. Because practice can vary, and numbers consulted are usually small, our snapshots can be unfocused and fuzzy. It is rare to have a high-definition picture, gained through detailed study, providing quality, size, and validity. One such provides a super picture of how hip and knee arthritis in older people is treated in the UK [1].

Study

Data were from the MediPlus primary care database in the UK, with about three million anonymised patient records. Practices with complete data up to 2002 formed the study group, about 60% of the total. The cohort was defined as people aged 65 or above who had a first consultation about a knee or hip condition in 1996 to 1998.

For inclusion there was a requirement of at least three years of records before and after the consultation, with problems in hip or knee (but not both together). Excluded were people with previous history of arthritis, chronic conditions likely to produce hip or knee problems, like rheumatoid arthritis, previous surgery, or recent evidence of trauma. Records were followed for three years from the consultation and information about tests, referrals, and therapy extracted.

Results

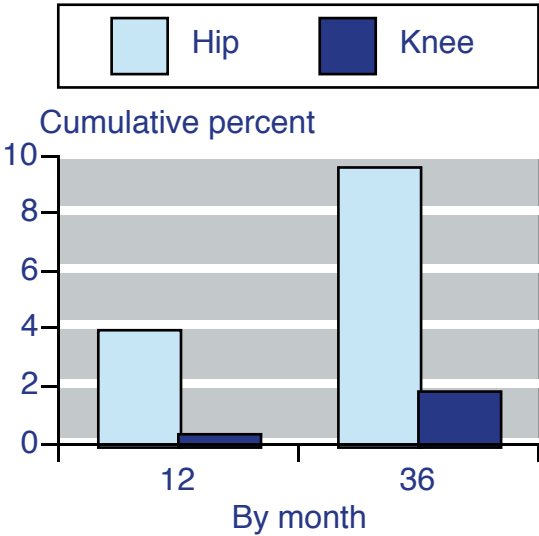
There were 311,000 people aged 65 years or older. In the cohort, there were 5,600 initial consultations for a hip problem,

Table 1: Referrals and medical treatments over one year in over-64s

	Total or percent		
	Cohort	Hip	Knee
Number	310,843	1,410	3,152
Referrals of any kind	8.7	18.7	16.9
Physiotherapy	2.0	3.8	3.8
Safer NSAIDs	6.7	12.3	13.9
Other NSAIDs	2.3	5.9	5.1
NSAID/GPA combination	1.1	1.0	1.3
COX-2	0.6	0.6	0.6
Topical NSAID	4.6	8.5	10.1
Codeine, tramadol	20.8	37.6	36.9
Anti-gout	0.9	2.1	1.8
Antacids	5.3	12.5	12.8
H2-antagonist	3.9	6.5	8.3
PPI	3.9	6.1	6.1
Antidepressant	5.0	8.3	8.1

For cohort the data are for 1998; for hip and knee the data are for one year before index consultation

Figure 1: Cumulative percent having joint replacement surgery



and 10,500 for a knee problem. When all the inclusion and exclusion criteria were applied, the final cohort had 1,410 people consulting for a hip problem, and 3,152 for a knee problem. Of these, about 65% were women, 35% were aged 75-84 years, and 7% aged 85 years or more.

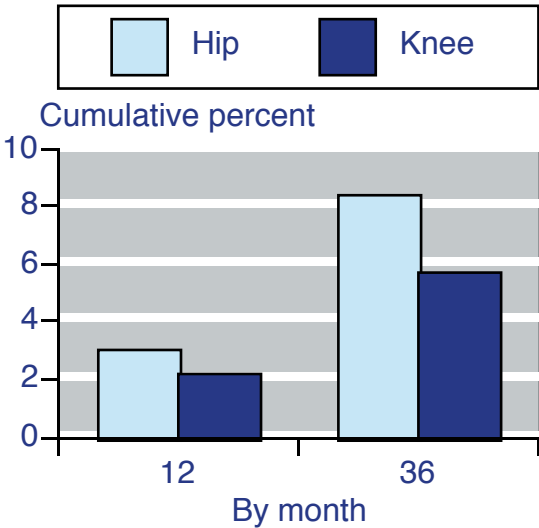
Whole initial cohort

Table 1 shows a selection of results for treatments for the whole cohort during 1998, and for the patients with hip or knee in the year before the index consultation. Hip and knee patients had higher rates of referrals, and were prescribed more NSAIDs, particularly topical NSAIDs, and codeine or tramadol, but were no more likely to receive a COX-2 inhibitor. Antacid and anti-ulcer drugs were also more commonly prescribed.

Hip problems

In the three years following an initial primary care consultation for a hip problem, about 40% of patients had been referred to medical or surgical consultation about the joint

Figure 2: Cumulative percent developing knee problem (with original hip problem, pale blue) or hip problem (original knee problem)



(Table 2), and one in 10 had had a joint replacement (Figure 1). About 1 in 12 of these patients had, by three years, also developed a knee problem (Figure 2).

Use of codeine analgesics, tramadol, safer oral NSAIDs and topical NSAIDs was common (Table 2), with other, less safe, oral NSAIDs, NSAID combined with gastroprotective agents, and COX-2 inhibitors less so. For these, for antacids and anti-ulcer drugs, and antidepressants, prescribing rates rose substantially over the three years after the initial consultation (Table 2).

Knee problems

In the three years following an initial primary care consultation for a knee problem, about 30% of patients had been referred to medical or surgical consultation about the joint (Table 3), and one in 50 had had a joint replacement (Figure 1). About 1 in 20 of these patients had by three years also developed a hip problem (Figure 2).

Prescribing of NSAIDs, oral and topical, codeine analgesics and tramadol, antacids and anti-ulcer drugs, and antidepressants all rose substantially over the three years (Table 3). Use of topical NSAIDs was higher in knee than hip patients, with use of codeine analgesics or tramadol rather less so.

In both groups there was also increased use of oral and injected corticosteroids (cumulative use about 7-10% of each for hip and knee). Use of morphine and similar analgesics was low, below 2%.

Comment

The results of this study are pertinent to the UK, and probably not for many other places in the world, because attitudes and practice patterns will differ markedly. Here more hip (10%) than knee patients (2%) underwent joint replacement within three years of first consultation. Elsewhere more patients may have received a joint replacement, and the difference between the proportions for knee and hip will be different.

But the methods used, and the size of the study, demonstrates the amount of information that can be derived from database studies, in order to help think about delivery of healthcare, and the capacity to deliver it. There's an old Irish joke about the tourist lost in rural Ireland who asks for help from a local, and gets the response: "If I wanted to go to Dublin I wouldn't start from here".

This study plonks a pin in the map from which one starts. It allows one to ask questions. In the discussion of this paper, for instance, the comment is made about adverse effects of medical treatments that carry high risks over the longer term. The data in this paper should be meat and drink for good health economic modelling of where we are now, and where we want to go.

Reference:

- 1 L Linsell et al. Prospective study of elderly people comparing treatments following first primary care consultation for a symptomatic hip or knee. *Family Practice* 2004 21: doi 10.1093/fampra/cmh609.

Table 2: Cumulative percentage of patients with hip problems being referred or having medical treatments over three years

	Cumulative percentage		
	First	12 months	36 months
Referrals of any kind	5.4	35.0	55.0
Referrals for joint	2.8	22.4	38.2
Physiotherapy	1.4	12.5	20.7
Safer NSAIDs	20.7	39.2	50.5
Other NSAIDs	4.6	12.2	16.8
NSAID/GPA combination	2.1	6.1	10.3
COX-2	1.4	3.6	7.7
Topical NSAID	6.1	18.0	28.8
Codeine, tramadol	31.6	65.9	79.4
Anti-gout	0.5	2.3	3.5
Antacids	1.6	14.4	22.4
H2-antagonist	1.9	9.9	16.4
PPI	1.1	8.1	17.7
Antidepressant	1.6	11.0	22.1

Table 3: Cumulative percentage of patients with knee problems being referred or having medical treatments over three years

	Cumulative percentage		
	First	12 months	36 months
Referrals of any kind	4.2	30.4	48.8
Referrals for joint	1.3	17.8	31.5
Physiotherapy	2.4	11.1	17.7
Safer NSAIDs	26.2	41.4	51.9
Other NSAIDs	4.3	10.2	14.3
NSAID/GPA combination	2.4	5.3	8.1
COX-2	0.9	2.6	6.0
Topical NSAID	15.7	27.8	36.9
Codeine, tramadol	25.0	57.3	72.3
Anti-gout	0.5	2.3	3.5
Antacids	2.0	14.1	22.1
H2-antagonist	1.8	9.7	15.3
PPI	1.3	7.6	14.8
Antidepressant	1.3	9.9	18.5

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SURGERY FOR MORBID OBESITY

Few people can be unaware that being overweight is a bad thing. It contributes to a range of conditions most of us would wish to avoid, including heart disease, stroke, hypertension, diabetes, cancer, arthritis, and asthma, to name but a few. Diet and exercise are the obvious ways forward, with anti-obesity drugs helping in some cases (Bandolier 121).

Morbid obesity has a definition, a BMI of 40 or more, or 35 or more in the presence of significant co-morbidities. A BMI of 40 for someone 1.8 metres (almost six feet) tall would mean a weight of about 130 kg (almost 300 lbs) or more. Here more extreme measures are suggested, including surgical therapy. A new systematic review and meta-analysis of surgical therapy in people massively overweight [1] indicates the results to be impressive, in terms of weight loss and other conditions. Intra-gastric balloon therapy was not included.

Systematic review

Surgical procedures were grouped into gastric banding, gastric bypass, gastroplasty, biliopancreatic diversion or duodenal switch, and other procedures. Studies of any design were sought as long as they had at least 10 subjects, had at least 30 days of follow up, and were in English.

Extensive searching looked for studies published up to July 2003. Outcomes looked for in addition to weight loss included one or more of diabetes, hypertension, hyperlipidaemia, or obstructive sleep apnoea. Mortality within 30 days was also sought. For some of the co-morbidities the outcome sought was whether the condition had resolved, or had resolved or improved. Resolved here meant the conditions either disappeared or no longer required therapy. For lipid disorders improved meant normalisation of laboratory values or discontinuation of therapy.

Results

There were 136 reports, five randomised studies, 28 non-randomised controlled trials or series, and 101 uncontrolled case series, with 22,000 patients in total. Patients in the studies had an average age of 39 years, and about 73% were women. The average BMI was 47 (range 32 to 69). These patients had high rates of comorbidity (Figure 1).

Figure 1: Comorbidity rates in people undergoing surgery for morbid obesity

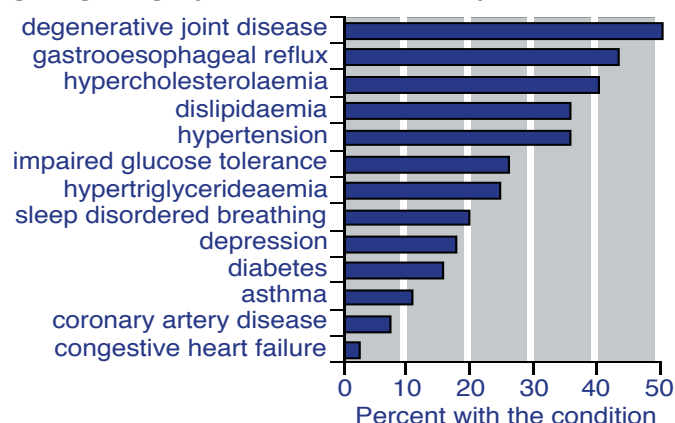


Figure 2: Average percentage of excess weight lost with four surgical techniques

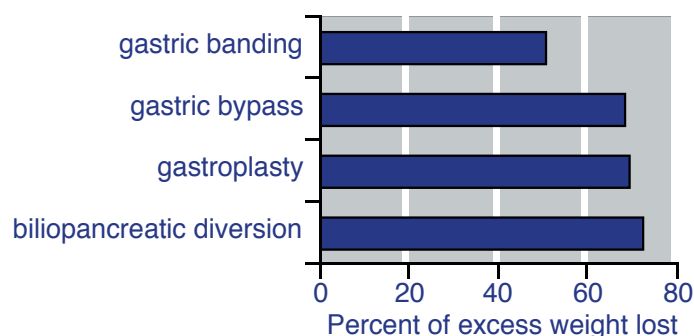
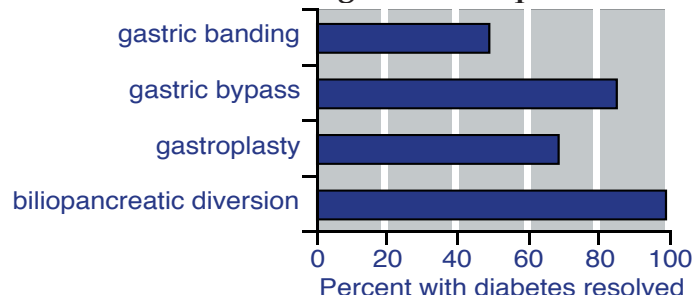


Figure 3: Percentage of people with diabetes resolved with four surgical techniques



Across all studies with about 10,000 reporting the outcomes, the absolute weight loss averaged 41 kg, and the BMI fell by 14 points. Weight fell by 36% of weight before the operation, and 65% of excess weight was lost. The percentage of excess weight (total preoperative weight minus the ideal weight) lost by each of the four techniques is shown in Figure 2.

Surgery also resulted in high rates of resolution or improvement in comorbid conditions like diabetes, hypertension, sleep apnoea, and lipid disorders (Table 1). In general, there were more substantial benefits with biliopancreatic diversion or duodenal switch, as for diabetes in Figure 3.

Laboratory values fell substantially. Total cholesterol fell on average by 0.5 mmol/L across all techniques, but the range for particular techniques was 0.2 mmol/L for gastric banding to 1.8 mmol/L for biliopancreatic diversion or duodenal switch. Fasting blood glucose fell by 4 mmol/L on average, and HbA_{1c} by 2.7%.

Mortality within 30 days was 0.1% for purely restrictive procedures (gastric banding or gastroplasty, about 3,000 patients), 0.5% in 5,600 undergoing gastric bypass, and 1.1% in 3,000 patients undergoing biliopancreatic diversion or duodenal switch.

Table 1: Overall average resolution or improvement rates for comorbid conditions

Condition	Percent		
	Resolved	Resolved or improved	Improved
Diabetes	77	85	
Hypertension	66	82	
Obstructive sleep apnoea	88	81	
Hyperlipidaemia			93
Hypercholesterolaemia			87

Not having thought about it too hard, Bandolier’s prejudices were that surgery for obesity was probably a waste of time. This review has shaken up those prejudices, thrown them out, and replaced them with evidence that very large beneficial changes follow surgery for morbid obesity. The weight losses recorded were huge, and the resolution or improvement in a wide range of conditions that too much flesh is heir to was close to spectacular.

A concern is that most of the evidence comes from case series, and not the randomised trials to which we are used. The overall numbers of patients and size of the outcomes are such as to overcome those qualms in most cases, though

there were only small numbers of patients in some of the subgroup analyses.

There were no health economic studies included. That is not too unexpected, but one doesn’t need a brain the size of a planet to see how the arguments are likely to go: costs of surgery in one column, saving in all those comorbid condition treatments for many years in the other. And finally, this type of surgery is now called bariatric surgery. It’s a new word to Bandolier, and we have no idea of its derivation. Perhaps there is an etymological genius out there who can enlighten us?

Reference:
1 H Buchwald et al. Bariatric surgery. A systematic review and meta-analysis. JAMA 292: 1724-1737.

INTRAVENOUS IMMUNOGLOBULIN FOR MS

Intravenous immunoglobulin for multiple sclerosis has excited interest because early, uncontrolled, studies seemed to show benefit. Because of the nature of the condition and the dearth of effective therapies, interest was natural, and led to small but inconsistent randomised trials. Bandolier looked at those trials in early 2002, and concluded that the evidence then available was insufficient. Large trials, of sufficient duration to prove the point were needed, and since 2002 two new trials have reported [1, 2].

One [1] was small, with 49 patients, comparing two doses of immunoglobulin with placebo over a year. It found benefits for immunoglobulin over placebo, but the numbers were very small, with no more than 17 patients in a group. A larger (318 patient) high quality study [2] now shows definitively the lack of benefit. It is worth visiting in some detail.

Randomised trial [2]

The trial recruited patients aged 18-55 years with secondary progressive multiple sclerosis, active disease, disease duration of at least three years, and an EDSS score of 3.0 to 6.5. The Expanded Standard Disability Scale (EDSS) at level 3 is moderate disability in one functional score or mild disability in three or four functional scores, though fully ambulatory, and at 6 is intermittent or unilateral constant assistance (walking stick, crutch, brace) required to walk about 100 metres with or without resting.

Secondary progression was defined as continued deterioration of disability for at least 12 months with or without interposed relapses after an initial relapsing-remitting course. Excluded were patients with an attack within 30 days of starting date, patients without MRI brain lesions consistent with multiple sclerosis, and various previous treatments, at least without a treatment-free period.

Recruited patients were randomised to intravenous immunoglobulin at 1 gram/kg per month up to a maximum of 80 grams, or 0.1% albumin in maltose. The last infusion was given at month 26. Randomisation was performed separately, and active and placebo treatments appeared identical. Concomitant treatments with immunomodulating or immunosuppressing drugs were not allowed.

Assessments were made every three months to 27 months, and MRI scans were taken at baseline and 12 and 24 months. Assessments were made by a neurologist who was not involved with treatment administration, and who was not allowed to discuss therapy or adverse events with the patient. The primary outcome was time to start of a confirmed treatment failure. This was a deterioration of 1 point on the EDSS score if it was initially below 6, or 0.5 points if it was 6 or higher. Other outcomes included a 20% worsening of a nine-hole peg test of arm functioning, and various functions of MRI imaging.

Results

Treatment and placebo groups were well matched at baseline. They had an average EDSS score of 5.2, and an average time of five years since the beginning of the secondary progressive phase of the condition. About half had had a relapse during the preceding 24 months.

Efficacy

There was no difference between the groups for any efficacy measure. The time to event analysis between immunoglobulin and placebo was identical, as was the total number with treatment failures, 20% deterioration on the peg test, or

Table 1: Efficacy and harm outcomes for IVIG in MS

Outcome	IVIG	Placebo
Efficacy		
Treatment failure (EDSS criterion)	77 (48%)	70 (44%)
Deterioration on peg test by 20%	55 (35%)	53 (33%)
Deterioration on EDSS and peg	98 (62%)	92 (58%)
Relapses	77 (48%)	83 (52%)
Harm		
All-cause discontinuation	39 (25%)	19 (12%)
Adverse effect discontinuation	10 (6%)	5 (3%)
Drug-related adverse events	113 (71%)	91 (57%)
Deep vein thrombosis	6 (4%)	1 (0.6%)
Pulmonary embolism	4 (3%)	0 (0%)

both, or clinical relapses (Table 1). The annual relapse rate was 0.5 in both groups. There were no differences between the groups on MRI imaging, though the total lesion load in the brain remained almost unchanged over two years in both groups.

Harm

More patients discontinued for any reason, or because of adverse events on immunoglobulin, than on placebo. Drug-related adverse events were common, but more so with immunoglobulin. These included infusion-related adverse events of fever, chills and headache, as well as rashes and eczema. Serious adverse events included deep vein thrombosis and pulmonary embolism, both of which occurred more frequently with immunoglobulin.

Comment

Strong negative trials are incredibly helpful because they give us a very positive signal that an intervention does not work in a particular condition. Strength means fulfilling the criteria of quality, validity, and size. This trial did just about everything to randomise and blind the study, and it

told us what happened to all the patients. It was large. It was valid, both by measuring a range of important outcomes, including objective outcomes obtained by brain scanning, and by being long. Its two-year duration ensured that it was trustworthy.

It tells us that there were no important benefits. It also tells us that there may be important harm, with serious adverse events of venous thrombosis and pulmonary embolism in one in 14 patients given immunoglobulin.

Most of the trials of immunoglobulin in multiple sclerosis have been in relapsing remitting disease. Their results have been mixed. Now all we need is an equivalent large and valid trial of immunoglobulin to settle the matter.

References:

- 1 M Lewanska et al. No difference in efficacy of two different doses of intravenous immunoglobulins in MS: clinical and MRI assessment. *European Journal of Neurology* 2002 9: 565-572.
- 2 OR Hommes et al. Intravenous immunoglobulin in secondary progressive multiple sclerosis: randomised placebo-controlled trial. *Lancet* 2004 364: 1149-1156.

REDUCING LATEX ALLERGY

Bandolier's interest in latex goes back almost a decade, when a review of latex allergy was posted on the Internet site, and when the problem was not well recognised. A new study from Germany shows how tackling the problem on a national level can have a major impact [1].

Study

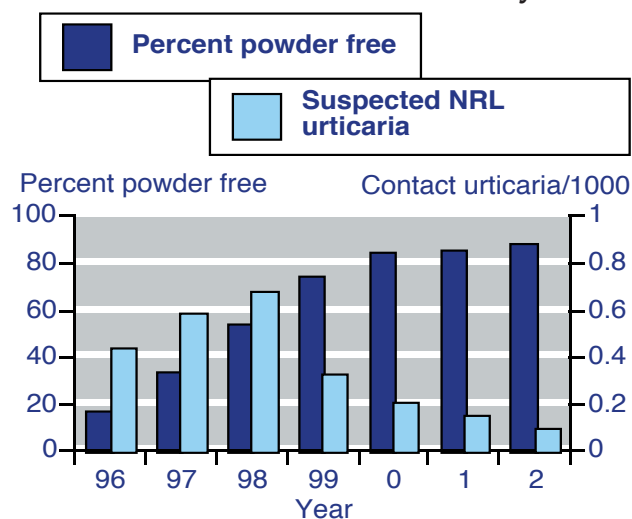
In Germany, a law of 1997 allowed mandated use of low-allergen, powder-free natural rubber latex gloves. The number and type of gloves purchased in Germany was provided by manufacturers. Statutory accident insurance covers almost two million German healthcare workers, and suspected occupational diseases have to be reported to the accident insurance company. Reported cases are required to have a medicolegal examination including hypersensitivity tests, with skin prick and IgE for latex allergens.

Results

Purchase of sterile and non-sterile gloves increased considerably from 1986, reaching a plateau from 1996. The proportion of gloves made of latex (powdered or unpowdered) rose, as gloves made from vinyl, polyethylene or copolymer decreased because of concerns that they were much less biodegradable, and were hazardous when incinerated.

The proportion of powdered gloves was high (above 80%) before 1996, and fell thereafter. The figures for acute care hospitals in Germany are shown in Figure 1, and the proportion of powdered gloves fell from above 80% in 1996 to about 10% by 2002. In response the incidence of latex-induced contact urticaria fell dramatically (Figure 1). There were similar falls, from over 0.3 to below 0.1 per 1000 workers in all healthcare settings.

Figure 1: Increased use of powder-free gloves and contact urticaria rates in Germany



Comment

Strengths of the study were size (two million healthcare workers), that the type and number of gloves purchased was known, that reporting occupational health problems was mandatory, with objective diagnosis. Using powder-free gloves removes air-borne allergens, and decreased latex-related contact urticaria. Simple and practical measures properly instituted make a difference. The reduction from 0.35 to 0.07 cases of contact urticaria per 1000 workers for the 1.8 million workers in the insurance scheme saves 500 people a year from lost working time and personal distress.

Reference:

- 1 H Allmers et al. Decreasing incidence of occupational contact urticaria caused by natural rubber latex allergy in German health care workers. *Journal of Allergy and Clinical Immunology* 2004 114: 347-351.